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10/073,463	02/11/2002	Andrey Rzhetsky	AP34006 070050.1942	4349

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EXAMINER

DEJONG, ERIC S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/073,463	Applicant(s) RZHETSKY ET AL.	
	Examiner Eric S. DeJong	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18,19,21,25-29,31-33 and 36-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-45 is/are rejected.
- 7) ☒ Claim(s) 36,38 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/14/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED OFFICE ACTION**

The instant application has been assigned to a different examiner.

It is acknowledged that the numbering of claims 1-45 have been amended by applicants to properly reflect their original numbering in accordance with 37 CFR § 1.126.

### ***Election/Restrictions***

Amended claims 18, 19, 21, 25-29, 31-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, claim 18 has been amended to recite a method for identifying a most likely biological pathway for a set of interacting molecules comprising the steps of representing a set of interacting molecules as an oriented network graph, assigning a probability to each possible oriented network graph, and selecting an oriented network graph as the most likely biological pathway. As such the invention of claims 18, 19, 21, 25-29, and 31-33 is drawn to the generation and use of oriented network graphs. In contrast, the invention as originally claimed and as recited in claims

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36-45 does not involve the generation or use of oriented network graphs. As such, the invention of claims 18, 19, 21, 25-29, and 31-33 is not coextensive in scope with the invention of claims 36-45. Further, the invention of claims 18, 19, 21, 25-29, and 31-33 has a materially different design, mode of operation, and effect than that of the invention as originally filed and as recited in claims instant claims 36-45.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18, 19, 21, 25-29, and 31-33 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Objections***

The previous rejection of claim 37 because of minor claim informalities is withdrawn in view of amendments made to the instant claims.

Claims 36, 38, and 44 are objected to because of the following informalities:

Regarding the form of a claim, the MPEP § 608.01(m) states:

“Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995).”

Claims 36, 38, and 44 use periods other than at the end of the claim or for abbreviations. See lines 6, 9, and 11 of claim 18, lines 7, 13, 17, 22, 25, and 27 of claim

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36, lines 6, 7, 10, and 12 of claim 38 and lines 4, 6, and 8 of claim 44. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The previous rejection of claims 36-45 under 35 USC § 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of arguments presented by applicants.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 recites the limitation “the known biological system networks” in lines 11 and 12 of the instant claim. There is insufficient antecedent basis for this limitation in the claim. It is acknowledged that line 3 of claim 36 recites “a known biological system, however this does not provide a proper antecedent basis for the “the known biological system networks”.

Claim 36 recites the limitation of “determining attraction probabilities between pairs of molecules of the set of interacting molecules based on known molecular interaction data” in lines 7 and 8 of the instant claim. Claim 36 recites further recites the

limitation of “said attraction probabilities are determined by quantifying the occurrence frequency of said conserved features of said pair of molecules immediately upstream or downstream of each other” in lines 9-11 of the instant claim. As such, claim 36 recites two distinct ways in which “attraction probabilities” are determined, one based on known molecular interaction data and another based on quantifying frequency occurrence of conserved features. This causes the metes and bounds of the claim to be indefinite as it is unclear which of the two ways for determining “attraction probabilities” is required.

Claim 36 recites the limitation of “an edge probability  $P(E)$ ” in line 13 of said claim. The metes and bounds of this limitation are indefinite because neither the instant claim nor the instant disclosure provide a definition for what “an edge probability” actually represents. The indefiniteness of the limitation “edge probability” is further compounded by the recitation of “determining an edge probability... based on the determined attraction probabilities” (see lines 13-15 of the instant claim) as the meaning of the term “attraction probability” is unclear for the reasons provided above.

Claim 36 recites the limitation of “a topology probability” in line 17 of the instant claims. Claim 36 further recites the limitation of “said topology probability being a product of an incoming edge distribution probability and an outgoing edge distribution probability” in lines 19 and 20 of the instant claim. However, the metes and bounds of these limitations are indefinite as neither the claim nor the instant specification provide a definition for what “an incoming edge distribution probability” or “an outgoing edge distribution probability” is intended to mean or encompass.

Claim 36 recites the limitation of “determining a network probability... as a product of said edge probability  $P(E)$  and said topology probability  $P(\text{topology})$ ” in lines 22-24 of the instant claims. The metes and bounds of this limitation are indefinite however, as definitions of the terms “edge probability  $P(E)$ ” and “topology probability  $P(\text{topology})$ ” are not provided by the disclosure nor is the meaning or scope of these terms apparent from either the instant claims or the instant specification.

Claim 36 recites “determining a posterior probability” in line 25 of the instant claim. The metes and bound of this limitation are indefinite as neither the claims nor the instant specification provide a definition of what a “posterior probability” actually means or encompasses.

Claim 37 is also included under the above rejection due to its dependence from claim 36.

Claim 38 recites the limitation of “determining attraction probabilities” in line 7 of the instant claim. The metes and bounds of this limitation is unclear as neither the claim nor the instant specification set for a definition for what an “attraction probability” actually is or how to determine an “attraction probability” in the context of interacting molecules nor is this term apparent from either the instant claims or the instant specification

Claim 38 recites the limitation of “molecular interaction probabilities” in line 10 of the instant claim. The metes and bounds of this limitation is unclear as neither the claim nor the instant specification set forth a definition for what an “molecular interaction

probability” actually is or how to determine a molecular interaction probability. The indefiniteness of this limitation is further compounded by the recitation of “determining molecular interaction probabilities... based on the attraction probabilities” (see lines 10 and 11 of the instant claim), as the meaning of the term “attraction probability” is unclear for the reasons provided above.

In claims 39-42 the recitations of equations merely by number render the rejected claims vague and indefinite. These instant specification do not set forth what the variables used in equations 5, 6, 14, and 17 intended to represent in the context of defining the domain of biomolecules or how these equations are to be used for the ultimate goal of identifying a most likely biological pathway. The recitation of using an equation or set of equations wherein variables are not sufficiently defined does not set forth a clear and concise limitation of what steps one of skill in the art is required to perform in order to use the instantly claimed method.

Claims 44 and 45 are also included under the above rejection due to their dependence from claim 38.

### ***Claim Rejections - 35 USC § 101***

The rejection of claims 44 and 45 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn because the instant claims involve a physical transformation step of contacting a test compound to at least two molecules.



35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 36-43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 36-43 are drawn to a process. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result . Furthermore, the claim must be limited only to statutory embodiments.

Claims 36-43 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a readily accessible memory or other computer on a network, or by including a physical transformation.

Claims 44 and 45 rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

Instant claim 44 recites the limitation of "identifying an interaction between said at least two molecules using the method of claim 38". However, in performing the method of claim 38 only an identification of a probability of interaction results rather than an actual one. Further, instant claim 38 does not require any step wherein predicted interactions are confirmed, nor does practicing the method of claim 38 provide a result wherein proteins or molecules are made, selected or purified such that they can be contacted with any test compound. Therefore, one of skill in the art would be required to identify and confirm the utility of any probable interaction between any two given molecules by performing further research, mathematical calculations, and steps to determine a "use" of molecules that may actually have a predicted interaction. Utilities that require further research to identify or reasonably confirm a "real world" context of use are not substantial utilities (See M.P.E.P. 2107.01). As set forth in *Brenner v. Mason* (148 U.S.P.Q. 689 (1966)) and *In re Ziegler* (26 U.S.P.Q.2d 1600), the "usefulness" of an invention must be immediately apparent to those familiar with the technological field of the invention. Since, the result of the instantly claimed invention is not "immediately useful", it therefore lacks utility.

Claims 44 and 45 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Response to Arguments***

Applicant's arguments filed 11/14/2005 have been fully considered but they are not persuasive.

In regards to the rejection of claims under 35 USC §101 as being drawn to non-statutory subject matter, applicants argue that the instant claims have been amended so that they are directed to computer readable medium for realizing the functionality of the inventive computational methods.

In response, it is noted MPEP § 2106 regarding computer related inventions states:

"Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance. In re Sarkar, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978) ("[E]ach invention must be evaluated as claimed; yet semantogenic considerations preclude a determination based solely on words appearing in the claims. In the final analysis under 101, the claimed invention, as a whole, must be evaluated for what it is.") (quoted with approval in Abele, 684 F.2d at 907, 214 USPQ at 687). See also In re Johnson, 589 F.2d 1070, 1077, 200 USPQ 199, 206 (CCPA 1978) ("form of the claim is often an exercise in drafting"). Thus, nonstatutory music is not a computer component and it does not become statutory by merely recording it on a compact disk. Protection for this type of work is provided under the copyright law."

As such, an amendment to the claims wherein the recited method comprises using a computer to execute a set of instructions disposed on computer readable media does not by itself render the claim statutory. Rather, the determination of whether a claimed process is statutory or non-statutory requires consideration of the method that results from executing the set of instructions disposed on computer readable media. In the instant case, the process as claimed does not require any physical transformation step

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nor does practicing the claimed method provide a result that is useful, tangible, and concrete.

In regards to the rejection of claims under 35 USC § 112, second paragraph, as being indefinite, applicants argue that the instant claims have been amended are clear, definite and fully conform to all requirements of 35 USC § 112. Applicants further cite paragraphs 0020 and 0035.

In response, it is noted that certain terms recited in the rejected claims are discussed in paragraphs 0020 and 0035 and throughout the disclosure. However upon review of the instant specification, the disclosure fails to provide definitions for the limitations identified in the above rejection of claims under 35 USC § 112, second paragraph, that render the claim indefinite. Further, it is unclear from a review of the instant disclosure what the meaning or intended scope of the above identification limitations in the context of identifying biological pathways. Further, the lack of clarity in the claimed terminology has precluded a search of the prior art, as it cannot be ascertained what the instantly claimed method steps actually require one of skill in the art to perform.

In regards to claims 44 and 45, applicants argue that the drug screening procedure of claim 44 does not require “wet contact” experiments as all steps of the procedure of claim 44 may be conducted computationally as can be understood from the context of the specification.

In response, it is noted that instant claim 44, step b recites “introducing a test compound in the biology network, the test compound contacting said at least two molecules”. As such, the instant claim requires literal contact of a test compound with at least two molecules of the biological network. As such, in practicing the claimed method, one of skill in the art would be required to perform a “wet step” wherein a real-world test compound is introduced and contacted with at least two-real world molecules selected from the molecules included in the biology network under investigation. The argument that the context of the instant claims can be understood from the context of the specification is not persuasive as limitations from the specification, although the claims are interpreted in light of the specification, are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As such, unless an explicit definition is provided in the disclosure the claimed terminology is given its plain meaning from the art.

Applicant's arguments filed 03/29/2006 have been fully considered but they are not persuasive.

In regards to the rejection of claims under 35 USC §101 as being drawn to non-statutory subject matter, applicants argue that the instantly claimed methods relate to the practical art of designing biomolecules. Applicants further argue that the rejection appears to be based on the unwarranted concern that the results of the claimed methods involve computation of probabilities and therefore are not useful tangible and concrete.

In response, it is noted that the instant claims are not directed toward designing biological molecules, rather the instant claims are drawn to method of identifying a molecular interaction (claims 36-43). As such, the claims do not require steps for or result in designing a molecule. Further, the basis of the instant rejection is not that the claimed methods involves computational procedures as asserted by applicants. Rather, the determination of the claims being drawn to non-statutory is based on the fact that claims 36-43 do not involve any physical transformation step nor do the instant claims produce a concrete and tangible result and practicing the instantly claimed method does not produce a tangible result (i.e.: a result that is outputted to a display or stored on readily accessible memory or other computer on a network).

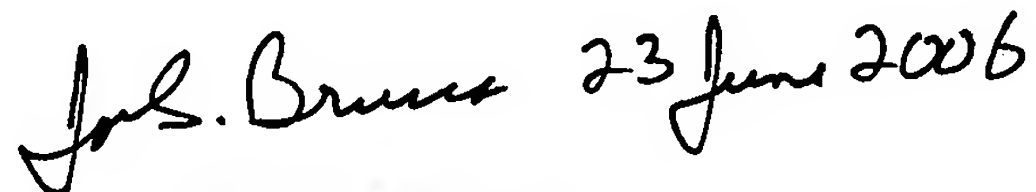
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDJ



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